

Appl. No. 10/661,640
Amdt. dated September 8, 2006
Reply to Final Office Action of June 8, 2006

REMARKS/ARGUMENTS

Applicants have received the Final Office Action dated June 8, 2006, in which the Examiner rejected claims 22-37 under 35 U.S.C. 102(b) as being anticipated by *Zabara* (U.S. Patent No. 5,025,807). With this Response, Applicants have amended claims 22, 24, 26, 27, 28, 29, 31, 33, 34, and 35, and canceled claim 25. Applicants have added new claims 38-40, which find support in the specification as filed. Based on the arguments and amendments contained herein, Applicant believes all claims to be in condition for allowance.

I. Claim Rejections under 35 U.S.C. § 112, Second Paragraph

The Examiner rejected claims 23-34 as being indefinite for failing to particularly point out and distinctly claim the subject matter, specifically noting that electrodes should be claimed as being “adapted to be” attached to a nerve, thereby avoiding claiming non-statutory subject matter. The claims have been amended to address this rejection.

II. The Rejections under 35 USC § 102(b) over Zabara

Claims 22–37 stand rejected as being unpatentable over U.S. Patent No. 5,025,807 (*Zabara*). The Examiner maintains that the disclosure of *Zabara* encompasses all of the structure of Applicants' claims.

As amended, each of claims 22-37 require at least two electrodes that bilaterally stimulate the right and left branches of the vagus nerve from a location in the vicinity of the patient's diaphragm. By contrast, the apparatus of *Zabara* describes a stimulation electrode coupled to the pulse generator and which is adapted for unilateral stimulation delivered to the vagus nerve in the neck, preferably in the vicinity below the inferior cardiac nerve. *Zabara* makes no mention of the right and left branches of the vagus nerve, nor delivery of bilateral stimulation to treat or relieve symptoms of movement disorders. It is respectfully requested that the Examiner take official notice that the vagus nerve branches at a location distal to the jugular foramen (at the base of the skull) and the branches take disparate routes thereafter, innervating various different organs, a fact that is not addressed by embodiments of *Zabara*. See, e.g., Gray's Anatomy of the Human Body, IX. Neurology, 5j. The Vagus Nerve, (20th Ed., 2000), available for reference at <http://education.yahoo.com/reference/gray/subjects/subject?id=205>). *Zabara*

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does not, therefore, disclose an apparatus adapted to administer bilateral stimulation to both branches of the vagus nerve, as it does not note the branching of the vagus nerve nor the positions of the right and left branches.

Claim 22 is currently amended to require at least two electrodes electrically coupled to the pulse generator, wherein the electrodes are adapted to be implanted in the patient's body and coupled to, respectively, one of the right and left branches of the vagus nerve of the patient at a location in a range from about two to about three inches above or below the patient's diaphragm, for alleviating symptoms of the movement disorder in the patient. Claim 22 is further amended to require that, when implanted, the two electrodes apply an electrical signal bilaterally to the right and left branches of the vagus nerve from a location in the vicinity of the patient's diaphragm. These amendments are supported in the specification at page 3; page 4, lines 1-7; page 7, lines 14-16; page 8, lines 9-18; page 9, 7-9; Figs. 1-2, for example. Claims 29 and 34 are currently amended in a manner analogous to the amendments to claim 23 and are similarly supported in the specification. Claims 24, 26, and 27 are currently amended for consistency with amended claim 22. Likewise, claim 31 is amended for consistency with amended claim 29. Applicants respectfully submit that claims 22-37, as currently amended, distinguish over *Zabara*.

III. New Claims

Claims 38, 39 and 40 are added with this amendment, and find support in the specification as filed. Analogous method claims have been allowed in the parent case which issued into U.S. Patent No. 6,622,038 ("Barrett '038"), specifically claims 1, 2, and 3 of Barrett '038. Thus claims 38-40 are believed to be in condition for allowance for at least the same reasons as claims 1, 2 and 3, respectively, of *Barrett '038*.

IV. Double Patenting Rejections

Examiner rejected claims 22-31 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,622,038. Applicant disagrees that the present claims are obvious over those of Barrett '038, but Applicants will submit an appropriate Terminal Disclaimer to obviate this non-statutory obviousness-type double

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patenting rejection. It is respectfully requested that the requirement for the Terminal Disclaimers be held in abeyance until the claims are considered to be allowable but for this ground of rejection.

Examiner also provisionally rejected claims 22-31 on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 23-37 of co-pending U.S. Application No. 10/661,641. Applicant disagrees that the present claims are obvious over those of the Barrett, '641 Application, but will timely file a terminal disclaimer upon indication of allowable claims in order to obviate this rejection.

V. CONCLUSION

This Response to final Office Action is filed in conjunction with a Request for Continued Examination. Reconsideration of the application and withdrawal of the rejections are requested in light of the foregoing amendments and remarks. Applicants request allowance of all pending claims. This is believed to be a full and complete response to the Final Office Action dated June 8, 2006. If any issue in the Office Action has been overlooked or is deemed to be incompletely addressed, Applicants respectfully request the opportunity to supplement this response. It is believed that no extensions of time or fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. In the event that any additional extension of time is necessary to allow consideration of this paper, such extension is hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required (including fees for net addition of claims) are hereby authorized to be charged to Deposit Account Number 503053 of Cyberonics, Inc., Houston, Texas.

Respectfully submitted,



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